

### **REMARKS**

Applicants wish to thank the Examiner for vacating all previous rejections and objections. Please reconsider the present application in view of the following remarks.

#### **Interview Summary**

Applicants thank the Examiner for clarifying that the rejection stated on page 7 of the Final Office Action dated April 18, 2011 was a paragraph mistakenly carried over from the previous office action. In the Interview Summary dated August 11, 2011, the Examiner reaffirmed that the rejection on page 7 was a mistake.

Accordingly, the only outstanding issues in this instant Office Action are the new matter and written description rejections.

#### **Disposition of the claims**

Claims 1 – 8, 11, 19, and 58 – 60 are currently pending. Claims 1, 7 and 8 are independent, the remaining claims depend, directly or indirectly, therefrom.

#### **Amendment to the claims**

Independent claims 1, 7 and 8 have been amended in this Reply to further clarify that the term “gene silencing effector” refers to an RNA that is capable of silencing a target gene when release in a cell. Support for this amendment can be found, for example, in the paragraph starting on page 6, line 7 through page 7, line 2.

Applicants submit that no new matter is introduced by this amendment.

**Rejections under 35 U.S.C. §112, 1<sup>st</sup> paragraph (new matter)**

Claims 1 – 8, 11, 19, and 58 – 56 stand rejected under 35 U.S.C. §112 as containing new matter. Applicants note the independent claims 1, 7, and 8 have been amended in this Reply. To the extent that this rejection may still apply, Applicants respectfully traverse.

In this instant non-final Office Action, the Examiner asserted that the newly introduced phrase “gene silencing effector” constituted new matter because the specification did not use or define this language. Applicants have amended claims 1, 7 and 8 to clarify that the phrase “gene silencing effector” refers to an RNA capable of silencing a target gene when release in a cell. This definition is clearly supported by Applicants’ specification and readily understood by those skilled in the art.

For example, in Figure 1, it is shown that the artificial intron in the isolated RNA has an insert that when spliced out inside of the cell can go on to effect gene silencing in the cell. Exemplary RNA of this insert, or “effector” include sense stRNA, antisense RNA, hairpin siRNA, ribozyme, etc. This is further elaborated in the first paragraph of the Detailed Description, where it is stated:

“...in some cases, the desired RNA is an antisense RNA that serves as an antisense oligonucleotide probe for antisense gene therapy. In other cases, the desired RNA molecule is translated into a polypeptide that is useful in gene replacement therapy. The desired RNA molecule can also consist of small antisense and sense RNA fragments to function as double-stranded siRNA for RNAi induction. Moreover, the desired RNA molecule can be a small hairpin-like RNA capable of causing RNAi-associated gene silencing phenomena. In addition, the desired RAN molecule can also be a ribozyme.”

Given the above explanation, those skilled in the art would have understood that the “gene silencing effector” is an RNA molecule having the ability to suppress a

targeted gene function either directly without translation or indirectly after being translated into polypeptides. Because the insert can “effect” a gene silencing effect in a cell, the meaning of the phrase “gene silencing effector” would be self-explanatory in the context of claims 1, 7 and 8.

In view of the above, Applicants submit that the phrase “gene silencing effector” is fully supported by Applicants original disclosure and does not constitute a new matter.

Accordingly, withdrawal of the rejection is respectfully requested.

**Rejections under 35 U.S.C. §112, 1<sup>st</sup> paragraph (written description)**

Claims 1 – 8, 11, 19, and 58 – 56 stand rejected under 35 U.S.C. §112 as failing to comply with the written description requirement. Specifically, the Examiner asserted that the phrase “gene silencing effector” encompasses a large genus whereas Applicants’ description only described 3 specific examples which could not constitute adequate written description support for the entire genus. Applicants respectfully disagree.

Independent claim 1 describes an isolated RNA containing an artificial intron which carries within it a “gene silencing effector.” Because claim 1 is directed to an RNA, those skilled in the art would have immediately recognized that the gene silencing effector is an RNA fragment within the isolated RNA. As far as the structure of the molecule is concerned, given a target gene, those skilled in the art would have been able to envision the various RNA sequences that can act as the gene silencing effector based on the various known gene silencing mechanisms such as RNAi, siRNA, tsRNA, etc. It is not necessary or practical to enumerate all the possibilities.

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In view of the above, Applicants respectfully submit that claim 1 is fully supported by the written description of Applicants' specification as originally filed. Therefore, claim 1 and its dependent claims 2 – 6, 11, 19 and 58 are all patentable.

Independent claims 7 and 8 have also been rejected as failing to be supported by Applicants specification because of the phrase "gene silencing effector". For at least the same reasons explained above, Applicants submit that independent claims 7, 8 and their dependent claims 59 – 60 are also fully supported.

Accordingly, withdrawal of this rejection is respectfully requested.

### CONCLUSION

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California telephone number (310) 595-3107 to discuss the steps necessary for placing the application in condition for allowance.

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Respectfully submitted,  
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